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Identification of biomarkers of clinical-risk deterioration in prehospital care

Submission date
20/02/2021

Recruitment status
No longer recruiting

Registration date
25/02/2021

Overall study status
Completed

Last Edited
23/04/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Time-dependent diseases (cardiac arrest, stroke, heart attack, sepsis and trauma) are one of the most frequent causes of medical consultation, activation of the emergency medical services (EMS), and consequently referral to the emergency department (ED).
The main objective of this study is to develop a specific score to be used in prehospital care with the ability to discriminate the risk of clinical deterioration from the initial moments of prehospital care.

Who can participate?
Patients attended by Advanced Life Support (ALS) in the community of Castilla y León.

What does the study involve?
Patients undergo a structured and objective evaluation according to protocol and proceed to its stabilization. Respiratory rate, saturation, heart rate, blood pressure, temperate, coma scale score, and a complete analysis is carried out (ions, blood gas, cardiac enzymes, coagulation and basic biochemistry) . Once the patient is left in the Emergency Department they follow the normal course of treatment. 30 days after the index event (ALSU's attention at the scene) an analysis of the electronic clinical history of the participant is made to collect data on their hospital care and mortality data. After one year of follow-up, a new data collection is carried out, in order to observe mortality from any cause, both in-hospital and out-hospital. At this moment, the observation will end. No interventions are performed on patients depending on the outcomes, but if the analytical or physiological data indicate urgent pathology, it will be acted on according to the EMS operating procedures. All participants receive the most appropriate treatment for their situation, regardless of the results of the study.

What are the possible benefits and risks of participating?
Through the use of early warning scale and biomarkers, the clinical safety of patients is increased since the health system can perform a comprehensive follow-up of their situation. The scale also uses language easily understood by patients and professionals, which helps to facilitate the transmission of information. A delay in the timely identification of the critical pathology of the patient has a direct impact on the health system, with an increase in diagnostic procedures and surgical techniques, hospitalizations, stays in intensive care units or unexpected

deaths. With the early identification of patients at high risk, it is intended to reduce morbidity and mortality. There are no known risks to participants taking part in this study.

Where is the study run from?
Health Emergency Management of Castilla y León (Spain), including 23 ALSU, and 14 hospitals, all belonging to the Public Health System of Castilla y León (Spain).

When is the study starting and how long is it expected to run for?
November 2020 to December 2024

Who is funding the study?
Regional Health Management of Castilla y León (SACYL) (Spain)

Who is the main contact?
Francisco Martín-Rodríguez
fmartin@saludcastillayleon.es

Contact information

Type(s)
Scientific

Contact name
Prof Francisco Martín-Rodríguez

ORCID ID
https://orcid.org/0000-0002-1773-2860

Contact details
Medicine Faculty
Avda. Ramón y Cajal, 7
Valladolid
Spain
47005
+34 686452313
francisco.martin.rodriguez@uva.es

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
A.200/a1

Study information

Scientific Title
Novel prehospital scores and outcomes based on biomarkers bedside: prospective, multicentric, ambulance-based, EMS-delivery, observational study

Acronym
preBIOs

Study objectives
Analyze all available biomarkers bedside or un route in order to develop an early warning score adapted to prehospital care, with the capacity to detect the risk of short-term deterioration in frail patients or the risk of early mortality from the index event.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 05/11/2020, Comité de Ética de la Investigación con Medicamentos Área de Salud Valladolid Este (Hospital Clínico Valladolid, Facultad de Medicina, Farmacología, C/ Ramón y Cajal, 7 47005 Valladolid, España; +34 983 42 30 77; alvarezgo@saludcastillayleon.es), ref: PI-GR-20-1970.
2. Approved 24/11/2020, CEIC Área de Salud de Valladolid Oeste (Hospital Universitario Río Hortega, 47012 Valladolid (Valladolid); +34 983 420 400; rconvi@saludcastillayleon.es), ref: PI217-20.
3. Approved 05/11/2020, CEIC Área de Salud de Salamanca (Complejo Asistencial Universitario de Salamanca, 37007 Salamanca (Salamanca); +34 923 29 11 00; comite.etico.husa@saludcastillayleon.es), ref: PI 2020 10 573

Study design
Prospective multicentric ambulance-based EMS-delivery observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Early mortality in all types of patients without evident signs of severity

Interventions
Once the patient (or legal guardian) signs the informed consent form, he/she becomes part of the study. Vital signs are taken and a blood sample is taken from the venous line, which is inserted due to the need of their own pathology, not for participating in the study. The prehospital analysis is then performed with this venous sample.
Patients and/or participants undergo a structured and objective evaluation according to protocol and proceed to its stabilization. The physiological variables are collected (respiratory rate, saturation, heart rate, blood pressure, temperate, coma scale score) and blood determination.

Intervention Type
Mixed

Primary outcome(s)

The following are evaluated at first attention at the scene of the incident:
1. Respiratory frequency, assessed using clinical observation at baseline
2. Oxygen saturation, assessed using a Physio LifePAK® 15 monitor at baseline
3. Heart rate, assessed using a Physio LifePAK® 15 monitor at baseline
4. Blood pressure, assessed using a Physio LifePAK® 15 monitor at baseline
5. Tympanic temperature assessed using a Braun model ThermoScan® PRO 6000 at baseline
6. Patient consciousness, assessed using the Glasgow Coma Scale at baseline
7. Use of oxygen (or not), evaluated using clinical observation at baseline
8. Analytical biomarkers: pH, pCO2, pO2, cHCO3-, BE (ecf), cSO2, Na+, K+, Ca++, Cl-, TCO2, Agap, AGapK, Hct, Hb, BE (b), Glu, Lac, BUN, Urea and Crea, assessed using EPOC Siemens Healthcare at baseline, cardiac enzymes (proBNP, myoglobin, CK, D dimer and troponin) with Roche Cobas 232 and INR with Roche coagucheck
9. Electrocardiogram assessed using a Physio LifePAK® 15 monitor at baseline
10. Initial and route FiO2 assessed using a Physio LifePAK® 15 monitor at baseline

The following are evaluated before arrival at the hospital:
1. Respiratory frequency, assessed using clinical observation at baseline
2. Oxygen saturation, assessed using a Physio LifePAK® 15 monitor at baseline
3. Heart rate, assessed using a Physio LifePAK® 15 monitor at baseline
4. Blood pressure, assessed using a Physio LifePAK® 15 monitor at baseline
5. Tympanic temperature assessed using a Braun model ThermoScan® PRO 6000 at baseline
6. Patient consciousness, assessed using the Glasgow Coma Scale at baseline
7. Use of oxygen (or not), evaluated using clinical observation at baseline
8. Prehospital diagnosis according to the Medical Priority Dispatch System incident code at baseline

Key secondary outcome(s))
1. Mortality at 1, 2, 7, 14 and 28 days
2. Presence of serious adverse events in prehospital scope at baseline
3. Presence of serious adverse events in hospital at 48 hours
4. Need for Intensive Care Unit at 30 days
5. Out-of-hospital mortality during a follow-up period of up to 1 year
6. Analytical data from the first blood draw at the hospital: leukocytes, hemoglobin, hematocrit, platelets, sodium, potassium, calcium, chloride, glucose, creatinine, bilirubin, CRP, PCT, troponin, D-dimer, proBNP and CK
7. Comorbidities
8. Triage level in the first contact in the emergency department

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Evaluated by an EMS
2. Transfer to hospital in advanced or basic life support.
3. Aged over 18 years
4. Provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Aged under 18 years
2. Cardiorespiratory arrest or exitus prior to arrival at the hospital
3. Pregnant
4. Psychiatric pathology
5. Diagnosis of end-stage disease (in treatment at a palliative care unit)
6. ALSU takes longer than 45 minutes to arrive
7. Do not require transfer to the hospital

Date of first enrolment
01/04/2021

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
Spain

Study participating centre
Gerencia de Emergencias Sanitarias de Castilla y León
C/ Antiguo Hospital Militar, s/n
Valladolid
Spain
47006

Study participating centre
Facultad de Medicina. Universidad de Valladolid
Avda. Ramón y Cajal, 7
Valladolid
Spain
47005

Sponsor information

Organisation
Junta de Castilla y León

ROR
https://ror.org/02s8dab97

Funder(s)

Funder type
Government

Funder Name
Junta de Castilla y León

Alternative Name(s)
Junta of Castile and León, Regional Government of Castilla y León, JCYL

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from (F. Martín-Rodríguez, fmartin@saludcastillayleon.es). Statistical data will be available from the end of the data collection phase for 4 years. The data may be shared with researchers carrying out similar studies, provided that the exchange of information is mutual, by sending the anonymized data of patients. Patients will have signed informed consent for data sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/08/2024	23/04/2025	Yes	No